ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 15 05 68169 007

Manufacturer: **Marine Polymer Technologies, Inc.**
107 Water Street
Danvers MA 01923
USA

EC-Representative: **EMERGO EUROPE**
Molenstraat 15
2513 BH The Hague
THE NETHERLANDS

Product Category(ies): **External Hemostatic Patch**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72102068

Valid from: 2015-08-23
Valid until: 2020-08-22

628650

Date, 2015-06-16

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Facility(ies):

Marine Polymer Technologies, Inc.
Suite B5, 461 Boston Road, Topsfield MA 01983, USA

Marine Polymer Technologies Inc.
159 Lorum Street, Tewksbury MA 01876, USA

Marine Polymer Technologies, Inc.
Suite 302, 1 Van de Graaff Drive, Burlington MA 01803, USA

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